UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/454,252	12/02/1999	JERRY PELLETIER	248/037	3544

7590 12/31/2002

Wesley B Ames
Foley & Lardner
PO BOX 80278
San Diego, CA 92138-0278

EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/31/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/454,252	PELLETIER ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *100-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *100,101 and 106-113* is/are allowed.

6)☒ Claim(s) *102-105,114 and 115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

File Copy

DETAILED ACTION

The request filed on October 21, 2001 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/454252 is acceptable and an RCE has been established. An action on the RCE follows.

Status of the Claims

Applicants' response to office action dated July 12, 2002 (paper# 18) filed on October 21, 2002 is acknowledged. Claim 102 has been amended and entered. Therefore, claims 100-115 are currently pending to which the following grounds for rejection are or remain applicable.

Information Disclosure Statement

The information disclosure statement filed on October 21, 2002 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because the copies of the references listed in PTO Form 1449, are missing from the application. Therefore the information referred to therein has not been considered as to the merits. Applicants have stated in RCE (paper# 21) that copies of cited references submitted in parent application 09/407804, however the references are not present in the parent application.

Response to Remarks and Arguments

Withdrawal of Objections/Rejections

Claims 100 and 106 rejected under **35 U.S.C. 112, first paragraph** is withdrawn in view of Applicants' amendment to claims (paper #15).

Claim 101 rejected under **35 U.S.C. 112, first paragraph** is withdrawn in view of Applicants' remarks at page 4 (paper #20) and submission of PCT publications (WO 02/50106, WO 02/50545, and WO 02/44718) in support of assay conditions.

Claims 107-113 rejected under **35 U.S.C. 112, first paragraph** is withdrawn in view of Applicants' remarks at page 5 (paper #20) and submission of PCT publications (WO 02/50106, WO 02/50545, and WO 02/44718) and US 6,376,652 in support of plurality of bacteriophage polypeptides, plurality of bacterial targets, or plurality of bacteria.

Claims 100-114 rejected under **35 U.S.C. 112, second paragraph** is withdrawn in view of Applicants' amendment to the claims (After Final Amendment, paper #15).

Claim 102-105 rejected under **35 U.S.C. 112, second paragraph** is withdrawn in view of Applicants' amendment to the claims (After Final Amendment, paper #15).

Maintenance of Objections/Rejections.

Rejection under 35 USC § 112, First Paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 102-105, 114 and 115 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specifically disclosed method for identifying a target for antibacterial agent comprising a) contacting a bacterial protein with a bacteriophage polypeptide that inhibits bacterial growth; b) determining the binding of said bacteriophage polypeptide to the said bacterial protein c) identifying said bacterial protein bound by said bacteriophage polypeptide, as set forth in the specification, does not reasonably provide enablement for all methods for identifying bacterial targets of all bacteriophage inhibitor protein fragments, having all structure or all variation. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 102-105 and 115 are directed to a method identifying a bacterial target protein that binds to a fragment of bacteriophage polypeptide. No biological activities were attributed to the recited protein fragments and the structural information was limited. There is no disclosure about the binding activities of claimed fragments. Applicants assert on page 8, lines 3-8 of the Amendment filed on December 26, 2001 (paper #13) that using the procedure described in the present application 6 proteins derived from phage 77 were identified which inhibit bacterial growth in solid and liquid assays. Identification of these inhibitor ORFs is described in the specification of the parent application 09/407804 and also in PCT Publication WO 0146383, however none of the references provides any description or demonstration of a method identifying a bacterial target protein that binds to a fragment of bacteriophage polypeptide. It would require undue experimentation for a person having ordinary skill in the art to be able to practice the claimed invention because no guidance has been provided such that a person having ordinary skill in the art would know the structure with reference to the binding site of any fragment of the bacteriophage inhibitor protein. There is no description given for a binding assay wherein it demonstrates the binding of a fragment of bacteriophage inhibitor protein to a bacterial target protein. Applicants assert on page 3 lines 12-22 (paper #20) that the methods for determining whether a bacteriophage protein inhibits bacterial growth can also be used to determine whether a fragment of that bacteriophage protein retains the bacteria-inhibiting property. Applicants' arguments have been noted but not found persuasive because the specification fails to demonstrate a bacteriophage protein fragment that inhibits the bacterial

growth, determined by the method claimed. The amended claim recites that active fragment retains the bacteria-inhibiting property of said bacteriophage polypeptide, however, the specification fails to describe or demonstrate such active fragments that retain the bacteria-inhibiting property of the full-length protein. Therefore, amended claim does not obviate the rejection.

Response at page 4 (paper #20) asserts the published examples in PCT publications (WO 02/50106, WO 02/50545, and WO 02/44718) and US 6,376,652 describe the identification of 3 different targets using 3 different inhibitory bacteriophage proteins. Further, Applicants assert that these examples demonstrate that the present methods have been successfully applied, and confirm that the inclusion of specific examples applying the claimed methods is not necessary for one of ordinary skill in the art to carry out the claimed invention. The arguments in the response have been fully considered but not found persuasive because above publications have not disclosed a fragment as an example that demonstrate that the present methods have been successfully applied, therefore, it requires experimentation for the inclusion of fragments as specific examples applying the claimed methods is necessary for one ordinary skill in the art to carry out the claimed invention.

Regarding claims 102-105 and 115, the response at page 5 (Paper #20) asserts methods of making fragments of known proteins are readily carried out using conventional molecular biology methods. Further, binding and inhibitory activity assays with fragments can be carried out using the same techniques described for full-length inhibitory bacteriophage polypeptides. The arguments have been fully considered but not found persuasive. Neither the specification nor the published examples (supra) have given any guidance to develop such specific fragments with

inhibitory and/or binding activity that can be used to detect binding to bacterial proteins. No guidance is available to determine the binding site of any fragment of bacteriophage inhibitor protein. Therefore undue experimentation is required to practice the invention.

Claim 114 is directed to a method of identifying a fragment of bacterial target protein to which said bacteriophage polypeptide binds. No biological activities were attributed to the recited protein fragments and the structural information was limited. Specification fails to provide a specific description for the condition of the assay for the binding of a fragment of bacterial target protein to bacteriophage inhibitor protein. There is no disclosure about the binding activities of claimed fragments. A partial proteolytic fragment of DnaI interacting with the 77ORF104 was demonstrated in WO 01/46383 (page 59, Example 3). This demonstration does not reasonably provide enablement for any method for identifying any fragment of bacterial protein, having any structure or any variation to which any bacteriophage polypeptide binds. In response it is asserted at page 5 (paper #20) that fragments can be constructed using conventional molecular biology and/or prteolytic techniques, and the fragments can be tested for binding to the inhibitory bacteriophage protein in the same way the full-length bacterial protein is tested using techniques described for full-length inhibitory bacteriophage polypeptides. The arguments are not found persuasive because specification fails to provide any guidance for the development of bacterial protein fragment that would retain the specific binding activity for binding to the inhibitory bacteriophage protein.

Therefore, in view of the degree of guidance given in the specification and the limited exemplification of the method using bacteriophage inhibitor protein, coupled with the unpredictability associated with sequence prediction based on activity, it would require undue

experimentation for a person having ordinary skill in the art to be able to practice the claimed invention without further guidance.

Conclusion

Claims 102-105, 114 and 115 are rejected. Claims 100, 101 and 106-113 are allowable.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Rita Mitra, Ph.D.
December 25, 2002